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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/816,938	04/05/2004	Baiyang Wang	1861.1670002/JUK/AWL	3825

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EXAMINER	
SZPERKA, MICHAEL EDWARD	
ART UNIT	**PAPER NUMBER**
1644	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	01/10/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/816,938	WANG, BAIYANG	
	Examiner	Art Unit	
	Michael Szperka	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 November 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-81* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-81* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's preliminary amendment received November 9, 2004 is acknowledged.

Claims 73-81 have been added.

Claims 1-81 are pending in the instant application.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-10, 12-28, 36, 37, 52-62, 73-77, and 81, drawn to antibodies, hybridomas and kits that are specific for human tissue factor (TF), classified in class 424, subclass 141.1.

II. Claim 11, drawn to anti-antibodies, classified in class 530, subclass 387.2.

II. Claims 29-34 and 78-80 drawn to methods of treating cancer, classified in class 424, subclass 143.1.

IV. Claim 35, drawn to methods of making hybridomas, classified in class 435, subclass 346.

V. Claims 38-49, drawn to nucleic acids, vectors and their host cells, classified in class 536, subclass 23.1.

VI. Claims 50 and 51, drawn to methods of making antibodies recombinantly, classified in class 435, subclass 326.

VII. Claims 63 and 64, drawn to methods of delivering pharmaceuticals to patients, classified in class 424, subclass 141.1.

VIII. Claims 65-70, drawn to methods of educating consumers, classified in class 514, subclass 8.

IX. Claims 71-72, drawn to methods of identifying and commercializing pharmaceuticals, classified in class 514, subclass 2.

The inventions are distinct, each from the other because of the following reasons:

3. Inventions I, II, and V are directed to related products. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have different physical structures and uses. Specifically, the structure of antibodies and nucleic acids are distinct, with these differences in structure give rise to unique functional properties, such as antibody binding which is a property of antibodies but not nucleic acids. Further antibodies that bind other antibodies comprise distinct variable regions which give rise to distinct uses, such as their ability to be used as secondary reagents in immunoassays. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

4. Inventions III, IV, VI, VII, VIII, and IX are directed to related methods. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have different recited process steps, comprise distinct reagents, and achieve distinct goals and endpoints. For example, methods of making hybridomas for antibody production do not require knowledge of polynucleotide sequences, and similarly methods of making antibodies recombinantly do not require myeloma cells as fusion partners. Methods of making antibodies are not relevant to delivering pharmaceuticals or to educating people about pharmaceuticals. Methods of treating cancer can be performed by administering antibodies obtained directly from animals, such as polyclonal sera, administering antibodies produced by phage display technology, or by administering commercially available antibodies. Note that

pharmaceuticals can be delivered without educating and vice versa. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

5. Inventions (IV and VI) and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the products of group I can be made by either of the two patentably distinct indicated methods.

6. Inventions (I and (III, VII, and VIII)) and (V and VI) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the antibodies of group I can be used in methods of purifying TF rather than in methods of treatment. Note that methods of educating consumers do not necessarily require the product since the consumer need not ever have possession of the product, and methods of delivery are applicable to other antibodies and pharmaceuticals in general. Also note that the polynucleotides of group V could be used in methods of gene therapy so that antibodies of the recited specificity would be made by the recipient in situ rather than being administered exogenously. Therefore they are patentably distinct.

7. Inventions (II and (III, IV, VI, VII, VIII, and IX)) and (V and (III, IV, VII, VIII, and IX) are directed to an unrelated product and process. Product and process inventions are unrelated if it can be shown that the product cannot be used in, or made by, the process. See MPEP § 802.01 and § 806.06. In the instant case, the anti-antibodies of group II cannot be used in methods of making antibodies, treating diseases, delivering

pharmaceuticals, educating consumers, or identifying and commercializing anti-TF antibodies. Similarly the nucleic acids of group V are not made by or used in recited methods of treatment, hybridoma production, pharmaceutical delivery, education or discovery. Therefore they are patentably distinct.

8. Because these inventions are distinct for the reasons given above, because the literature searches required for Groups I-IX are not coextensive in that art that anticipates or renders obvious the invention of any one group would not necessarily anticipate or render obvious the inventions of the other groups, and because Groups I-IX have acquired a separate status in the art as shown by their different classification and divergent subject matter, restriction for examination purposes as indicated is proper.

9. This application contains claims directed to the following patentably distinct species of groups I and V. The species are the anti-TF antibodies generated by applicant. The species are independent or distinct because they differ in biological sequence. As such, applicant is to elect a single antibody (i.e. TF196, TF260, TF 278 etc...) as well as the biological sequences for the VH and VL domains of the elected antibody. An election of a pair of biological sequences without indication of the originating antibody, or election of the antibody without indication of which biological sequences read thereon will be held as non-responsive.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-10, 28, and 73-77 are generic.

10. This application also contains claims directed to the following patentably distinct species of group III. The species are the diseases to be treated with anti-TF antibodies. An example of recited species can be found in claim 31. These species are distinct because the diseases have distinct and non-overlapping patient populations, differ in

etiology, clinical progression and standard courses of treatment, and are recognized in the art as separate diseases.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 29, 32, 33, and 78 are generic.

11. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

12. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions

unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

13. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Szperka whose telephone number is 571-272-2934. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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January 5, 2007